

10/544259 IAPS Rec'd PCT/PTO 07 APR 2006

Atty. Dkt. No. MARKS0801 (041376-0801)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Alterschopfer and Watkinson

Title:

TRANSDERMAL

GRANISETRON

Appl. No.:

10/544,259

Filing Date: 08/03/2005

Examiner:

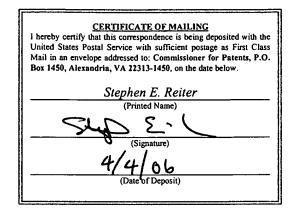
Not yet assigned

Art Unit:

1732

Conf. No.

1348



INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Mail Stop Amendment-IDS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

-1- 2

DLMR 282516.1

antedate or otherwise remove as a competent reference any document which is determined to be a prima facie reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language documents is described in the present specification. An English translation of the foreign-language documents is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

Respectfully submitted,

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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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AFR U 7	1006STATEMENT	BY APPLI	CANT	Filing Date	August 3, 2005	
.	ואָא			First Named Inventor	Peter Altenschopfer	
(%).				Group Art Unit		
RADEN	se as many sh	eets as ne	cessary)	Examiner Name		
Sheet	1	of	2	Attorney Docket Number	MARKS0801 (041376-0801)	_

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Publication of Where Relevant
Document Passages or Relevant Figures Appear
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			U.S	. PATENT APPLICATION DOCUM	MENTS	
Cyaminar	Cite No. ¹	U.S. Patent Application Document		Name of Detoctor or Applicant of	Filing Date of	Pages, Columns, Lines, Where Relevant
Examiner Initials*		Serial Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear

	FOREIGN PATENT DOCUMENTS										
Examiner Initials*	Cite No.1	Fo Office ³	reign Patent Document Number ⁴ Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶				
	A1	wo	94/07468	Cygnus Therapeutic Systems	04-14-1994	-					
	A2	wo	98/53815	Minnesota Mining and Manufacturing Company	12-03-1998	,					
	A3	wo	00/47208	Samyang Corporation	08-17-2000						
	A4	wo	01/74338	LTS Lohmann Therapie- Systeme AG	10-11-2001						
	A5	wo	04/069141 A2	Strakan Limited	08-19-2004						
	A6	EP	1064939 A	Novosis Pharma AG	06-26-2000						
	A7	JP	8-34731		02-06-1996						

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A8	Biswas and Rudra, Comparison of granisetron and granisetron plus dexamethasone for the prevention of postoperative nausea and vomiting after laparoscopic cholecystectomy. Acta Anaesthesiol Scand., 47:79-83, 2003.	

Examiner Signature		Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

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number SUPPLICATION DISCLOSURE
SUPPLICANT
SUPPLICANT Substitute for form 1449B/PTO Complete if Known **Application Number** 10/544,259 **Filing Date** August 3, 2005 **First Named Inventor** Peter Altenschopfer **Group Art Unit** as many sheets as necessary) **Examiner Name** 2 of Attorney Docket Number MARKS0801 (041376-0801)

	,	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A9	Cupissol et al., Evaluation of the bioequivalence of tablet and capsule formulations of granisetron in patients undergoing cytotoxic chemotherapy for a malignant disease. J.Pharm.Sci., 82:1281-1284, 1993.	
	A10	Friedman et al., Oral granisetron for the prevention of acute late onset nausea and vomiting in patients treated with moderately emetogenic chemotherapy. Oncologist, 5:136-143, 2000.	
	A11	Gralla et al., Recommendations for the use of antiemetics: Evidence based, clinical practice guidelines. Journal of Clinical Oncology, 17:2971-2994, 1999.	
	A12	Guillem et al., High efficacy of oral granisetron in the total control of cyclophosphamide-induced prolonged emesis. Proceedings of the American Society of Oncology, 17:46, 1998.	
	A13	Kalaycio et al., Continuous-infusion granisetron compared to ondansetron for the prevention of nausea and vomiting after high-dose chemotherapy. J. Cancer Res. Clin. Oncol., 124:265-269, 1998.	
	A14	Noble et al., A double-blind, randomized, crossover comparison of granisetron and ondansetron in 5-day fractionated chemotherapy: assessment of efficacy, safety and patient preference. Eur. J. of Cancer, 30: 1083-1088, 1994.	
	A15	Physicians Desk Reference (2001) entry for Kytril®	
	A16	Porzio et al., Pruritus in a patient with advanced cancer successfully treated with continuous infusion of granisetron. Support Care Cancer, January 21, 2004.	

Examiner Signature	,	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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